substantial evidence of limited life expectancy by reason of disease or advanced age. The administration of the drug to food-producing animals cannot be justified since it may result in residues of the drug in food.

(b) Drugs containing thorium dioxide are unsafe and are regarded as misbranded within the meaning of section 502(f) (1), (2), and (j) of the Federal Food, Drug, and Cosmetic Act when labeled or advertised for administration to man except when they have a unique clinical usefulness and there is substantial evidence of limited life expectancy by reason of disease or advanced age.

(c) Drug preparations containing thorium dioxide may be approved for marketing on the basis of new-drug applications containing labeling bearing, in addition to other requirements, information to the following effect, which differs substantially from the labeling that has been employed in the past in the marketing of such drugs:

(1) *Warning.* For use only when this drug has a unique clinical usefulness and there is substantial evidence of limited life expectancy by reason of disease or advanced age. Not for administration to food-producing animals.

(2) *Precautions.* Special precautions should be taken to prevent soft tissue extravasation of the injected material. Precautions should be taken to prevent injection of thorium dioxide into the subarachnoid space.

(3) *Indications for use.* For demonstration of primary or secondary tumors in the liver; for the delineation of the wall of a cystic malignant brain tumor when such delineation is deemed advantageous for purposes of progressive monitoring in the course of therapy.

(4) *Dosage.* Minimum amount necessary for adequate visualization should be utilized.

(d) A new drug application will be regarded as approvable if it contains appropriate labeling conforming to the provisions of paragraph (c) of this section and satisfactory information of the kinds required by § 314.50 of this chapter.

[40 FR 14033, Mar. 27, 1975, as amended at 55 FR 11577, Mar. 29, 1990]

§ 250.104 Status of salt substitutes under the Federal Food, Drug, and Cosmetic Act.

(a) As a result of reported poisonings from salt substitutes containing lithium chloride, under date of March 8, 1949, the Food and Drug Administration announced that it would regard each salt substitute as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, and that interstate distribution of each salt substitute should be discontinued until a new-drug application had been filed and become effective. Substantial information concerning the safety of many of the ingredients used in salt substitutes has been developed and published since the announcement was made. It is now possible to evaluate the safety of many individual salt substitutes and to determine whether they are new drugs requiring effective applications prior to distribution in interstate commerce.

(b) The Food and Drug Administration no longer regards all salt substitutes as new drugs. Upon request, the Administration will express its opinion whether a new-drug application is necessary for any particular product if complete information concerning its composition and proposed labeling is submitted.

§ 250.105 Gelsemium-containing preparations regarded as prescription drugs.

It is the consensus of informed medical opinion that the margin of safety between the therapeutic and toxic concentration of gelsemium is narrow and it is difficult to predict the point at which the dose will be toxic. Very small doses may cause toxic symptoms. It is therefore the view of the Food and Drug Administration that gelsemium is not a proper ingredient in any product that is to be sold without prescription. Accordingly, any drug containing gelsemium will be regarded as misbranded under section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act if its label fails to bear in a prominent and conspicuous fashion the statement ''Caution: Federal law prohibits dispensing without prescription.''